

Record Number(s)

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12/7/94 1/9/95
IN OUT

EFFICACY

FILE OR REG. NO. 64439-1

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 11/3/94

DATE OF SUBMISSION 11/3/94

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TYPE PRODUCTS(S): I, D, H, F, N, R^x, S

DATA ACCESSION NO(S) 434649-01

PRODUCT MER. NO. 14

PRODUCT NAME(S) MOLE-MED

COMPANY NAME Mole-Med

SUBMISSION PURPOSE Support claims made for product

CHEMICAL & FORMULATION 66% Castor Oil-and

 liquid formulation

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Efficacy Review: MOLE MED MOLE REPELLANT [sic] AND LAWN
PROTECTION, 64439-1
Mole-Med
Aurora, IN 47001

200.0 INTRODUCTION

200.1 Uses

INERT INGREDIENT INFORMATION IS NOT INCLUDED

A 66% Oil of Ricinus (Castor Oil) and [REDACTED]
[REDACTED] liquid mixture proposed for registration as a
"REPELLANT" to be used "for repelling Eastern moles and
Townsend's moles from lawns."

200.2 Background Information

See efficacy reviews of 6/19/90, 4/30/91, 2/25/93, and
5/3/94, along with other information in the product's jacket
and in a folder prepared by Daniel B. Peacock to track legal
actions pertaining to this product.

The material routed for my review consists of two EPA-
generated review cover sheets, four EPA-generated sheets of
paper pertaining to the initial rejection and ultimate
acceptance of the submission, an EPA-generated hand-written
note from the PM Team to the data submission screen people
recommending that the data submission be accepted in view of
the company's having supplied a GLP statement as required by
EPA, seven pages generated by the company for purposes of
complying with EPA's data submission formatting requirements,
a 4-page report of field efficacy trials, and a 1-page letter
dated 8/4/94 from the researcher to the registrant. Thus, I
have received 20 pages of material, but only 6 of these are
of any practical value: the 5 pages from the researcher and
the "PRAT-bean" cover sheet.

The 14 other pages represent much bureaucratic ado about very
little, culminating with the creation of a document, received
on 11/3/94, which states that the study "meets the
requirements for 40 CFR Part 160 (EPA's "Good Laboratory
Practice Standards" or "GLPs," 40 CFR, §160). The document
bears signatures "for" Dr. Glenn R. Dudderar and Dale Elshof,
but only Dudderar's name appears on the new study report.
(Both names had appeared on an earlier report discussed in
the efficacy review of 5/3/94.) The GLP certification page
also bears the signature of a Dr. Kenneth P. Reed who serves
as a registration agent for Mole-Med's and signed for the
company's president Eldon Pickett.

(Those interested in eliminating waste in government, halting
"non-essential" activities, and a paper-less office should
concentrate on OPP's red-tape and paper-generation policies

rather than looking for products to exempt from regulation or expansion of institutionally negligent policies such as notifications.)

201.0 DATA SUMMARY

The efficacy report was assigned the MRID # 434649-01. The report is attributed to Dudderar (alone) of Michigan State University and is entitled "The Effectiveness of Mole-Med in Preventing Mole Damage to Lawns." The research discussed in this report was performed "in southeast Michigan" during the months of May through July, 1994.

A total of 17 sites were monitored for mole activity. The sites represented four distinct "groups". Groups 1, 2, and 3 each consisted of three treated sites, and two control sites which were to be untreated. In each of these groups, one of the control sites was adjacent to a treated site while the other was separated from all other sites by a distance of at least 0.2 miles. Except for the one having an adjacent control site, all treated sites also were located at least 0.2 miles from the nearest other site. Group 4 is reported to have included two sites:

"The lawn of a farm house and a backyard wildlife feeding station." (Dudderar's house, perhaps?)

Sites were considered to be active if there were signs of restoration of subsurface mole tunnels purposely flattened (and probably marked) by research personnel. (It is not clear from the report whether the tunnels were flattened on three consecutive days or whether they were flattened once and checked for reconstruction three days later.)

In May, the only treatments made were at three sites in what probably was group 1. All of these sites and the two control sites showed mole activity 5 days prior to the date of treatment (5/15/94) and none showed signs of mole activity 5, 10, or 12 days after treatment. However, mole activity also was absent on the nonadjacent control plot after the time of treatment and was detected on the adjacent control site only in the 5-day posttreatment survey. In fact, the adjacent control site in group 1 was the only one of the 14 sites that were not treated on 5/15/94 where any mole activity was detected during the remainder of the month of May, despite the fact that mole activity was detected on 12 of these plots on 5/10. This "post-nontreatment" absence of mole activity was attributed to a drought that was reported to have lasted from 5/1 to mid June which caused the soil to be "dry and hard to a depth of over 4 inches" by 6/1/94.

The experiment was resumed after several days of rain beginning with a 3-inch thunderstorm on 6/14-15. Following these rains, mole activity was apparent at one of the three sites that had been treated on 5/15; on both of the group-1 control sites; on all of the non-control sites for groups 2, 3, and 4; and on both designated control sites for group 2. No mole activity was seen on group 3's control sites, while there were no designated control sites for group 4.

All designated treatment sites on which more activity was detected on 6/20/94, were treated with MOLE-MED on 6/21. Mole activity was not detected on any of these 9 sites on follow-up surveys completed on 6/24, 6/30, and 7/8. By 7/15, however, new mole activity was seen on 3 of the sites treated on 6/21 and on one of the two group-1 sites treated on 5/15 which had had no mole activity on 6/20. Following the treatment period of 6/21, mole activity was detected at 5 of 6 designated control sites, including 1 of the 2 group-3 sites where no mole activity had been detected on 6/20. The four treatment sites with mole activity on 7/15 plus the "adjacent control" site for group 2 were treated with MOLE-MED on 7/18/94. Five days later, no mole activity was detected at any of these 5 sites; and the only sites where mole activity was detected were 4 of the 5 remaining untreated control sites.

To summarize, all MOLE-MED treatments were followed by absences of detected mole activity for periods of time ranging from at least 19 days to no less than 69 days. As declines in mole activity following the May treatments were observed immediately in all but 1 of 12 plots where mole activity was apparent on 5/10, it should not be concluded that MOLE-MED was responsible for the declines in activity on the three treated plots. For assessing durations of treatment effectiveness from the 1994 study, we are then left with the results of the June treatments, which were not monitored more than 32 days after MOLE-MED application. These results of the June treatments are summarized below.

	TREATED SITES	CONTROL SITES
# SITES ACTIVE ON 6/20/94	10	4
#(%) TREATED ON 6/21/94	10 (100%)	0 (0%)
#(%) ACTIVE 6/24-7/8/94	0 (0%)	5 (125%)
% ACTIVITY CHANGE 6/21-7/8/94	-100%	+25%
#(%) ACTIVE 7/15/94	3 (30%)	5 (125%)
% ACTIVITY CHANGE 6/21-7/15/94	-70%	+25%

From the June treatments' results, it appears that use of MOLE-MED eliminated apparent signs of mole activity for 19-32 days. Dudderar claims that, during the Summer of 1994, mole activity remained absent at 4 of 5 sites that were treated with MOLE-MED in the Fall of 1993 for the Dudderar and Elshof (1993) study. Dudderar uses this information for suggesting that the effects of MOLE-MED can "last well beyond 73 days" which he feels that the 1994 work has supported. I find that the 1994 work only supports claims of repellency for 19-32 days. Therefore, I feel that the label should state that the effects of treatment may last from 2 weeks to a month or longer. Dudderar's letter of 8/4/94 states that heavy rains (<3" in 24 hr) may bring about a need for new treatments.

Dudderar reports that the short-term increases in mole activity following treatments observed in the 1993 were not seen in the 1994 trials. Because such effects have been observed, the statement which alludes to them should remain on MOLE-MED's label, although it could be softened from

"Mole activity increases temporarily as moles leave the treated area"

to

"Mole activity may increase temporarily as moles leave the treated area."

Dudderar's report and his letter of 8/4/94 suggest significant increases in mole activity (which he did not quantify) in areas adjacent to treated areas. Apparently because of such increases, a landowner persuaded Dudderar to treat one of the adjacent control sites.

The methods used for making treatments were not described. (In an earlier report, Dudderar and Elshof wrote that treatments were made "according to label directions".) Dudderar does report that treatments made in the wildlife feeding station site (group 4) included the soil plus "any food laying on the soil." Reportedly, the results of this treatment were that

"Not only did mole activity cease, but rabbits, squirrels, woodchucks, raccoons and skunks also stopped coming to the wildlife feeding site. Animals were seen to approach and then leave without feeding, and food on the ground was not consumed."

This anecdotal account is interesting and suggests areas for future product development but is not sufficient, by itself, to support the addition of claims for repelling animals other than moles to MOLE-MED's label.

202.0 CONCLUSIONS

1. The research report by Dudderar (1994), taken at face value, appears to support claims that MOLE-MED repels moles from (or inhibits subsurface digging activity in) treated areas. The demonstrated durations of such effects were between 19 and 32 days from the treatments made on June 21, 1994. Because of the confounding effect of the May-to-mid-June drought, it cannot be concluded that MOLE-MED was the sole or even the principal factor in eliminating evidence of mole activity following the treatments that were made on May 15, 1994.

The results of Dudderar's 1994 study would support a label claim that the product will repel moles for "two weeks to a month or longer." Users should be advised that retreatments, which appear to restore the original effectiveness, may be needed after heavy rains.

2. Because the increased digging observed in the 1993 trials was not seen in 1994, this effect may have been seasonal or simply something that does not always occur for some other reason. Because the effect is not an absolute certainty, the label statement which refers to it may be modified slightly to read

"Mole activity may increase temporarily as moles leave the treated area."

3. Dudderar's (1994) anecdotal account pertaining to the effects of MOLE-MED on species other than the eastern mole is interesting and suggests possible areas for future product development. His account is not sufficient, by itself, to support the addition of claims for repelling animals other than moles to MOLE-MED's label.
4. Any label changes which you seek to make as a result of the comments presented above must be proposed as amendments to this product's registration. Submit five (5) copies of proposed amended labeling if you seek to make any changes to this product's labeling.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
January 9, 1995